(Insert Health Care Agency)

MEDICAL DIRECTIVE: Pfizer-BioNTech COVID-19 Vaccine®

Original Date: (yyyy/mm)
Next Review Date: (yyyy/mm)
Contact Officer:
(Insert Agency Contact Officer)

Order/Delegated Procedure

Administer injectable Pfizer-BioNTech COVID-19 immunizations.

Recipient Clients

All individuals born in 2009 who are turning 12 before the end of the 2021 calendar year and older without contraindications to the Pfizer-BioNTech COVID-19 vaccine who live, work, or go to school in Ontario.[2,13]

Authorized Implementers

Health care providers of (Above named Agency) including nurses, nursing students under the supervision of a nurse, and contracted Agency Nurses in good standing with the College of Nurses of Ontario (CNO) and who have completed the required orientation, including a review of related policies, educations training at clinics and observation by the (Agency designate)

Indications

- Pfizer-BioNTech COVID-19 Vaccine (COVID-19 mRNA Vaccine) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe, acute respiratory syndrome coronavirus 2 (SARS- CoV-2) virus.[1]
- Clients must be born in 2009 and turning 12 before the end of the 2021 calendar year and older without contraindications to the vaccine.[1,13]
- The National Advisory Committee on Immunization (NACI) has developed evidence-informed guidance related to the prioritization of key populations in the context of limited vaccine supply to inform the planning of provincial and territorial publicly funded COVID-19 immunization programs.[3]

Contraindications

Clients are **NOT ELIGIBLE** for Pfizer-BioNTech COVID-19 vaccine under this medical directive if there is a risk of serious adverse reaction identified during their health assessment:

- A history of anaphylactic reaction to a previous dose of the Pfizer-BioNTech COVID-19

vaccine.[1]

- A history of proven immediate or anaphylactic hypersensitivity to any component of the Pfizer-BioNTech COVID-19 vaccine or its packaging.[1] Components of the Pfizer-BioNTech COVID-19 vaccine are listed in Appendix A.

The vaccine should not be administered in a general vaccine clinic. An urgent referral to an allergist/immunologist is recommended for these individuals. Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.[9]

Documentation using Ontario Ministry of Health and Long-Term care COVID-19 Vaccination: Allergy form after discussion with the health care provider is to be provided at the clinic including a vaccination care plan and **parameters the clinic should meet to provide safe vaccine administration.**[10]

Precautions

- As a precautionary measure, individuals who were diagnosed with myocarditis/pericarditis after a previous dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) should wait to receive their second dose until more information is available. The National Advisory Committee on Immunization (NACI), Public Health Ontario (PHO) and The Ministry of Health continue to follow this closely and will update this recommendation as more evidence becomes available.[14]
- Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g., intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the individuals.[2]
- Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g., foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.[2]
- Clients with a bleeding disorder should be optimally managed prior to immunization.[2]
- Clients currently experiencing moderate/severe, acute illness should have their vaccination postponed until the illness has resolved.[2]

Additional Special Considerations and Third Dose Eligibility

- The Vaccine Clinical Advisory Group, made up of clinical and public health physician experts, provided a recommendation to the Ministry of Health on the select populations which may be considered for third doses based on suboptimal/waning immune

response to vaccines and increased risk of COVID-19 infection. A risk/benefit analysis for individual patients is at the center of the collaborative clinician/patient decision-making process. Informed consent is required and should include (1) a review of the risks and benefits of a third dose of a COVID-19 vaccine, (2) a review of the potential risks /consequences of COVID-19 (3) a review of the risk of acquiring COVID-19 following the completion of a two-dose vaccine schedule in the population, (4) an acknowledgment of the limited or absence of evidence for the use of a third dose of the currently available COVID-19 vaccines in the population. **The individuals outlined below should receive a third dose of an mRNA vaccine (Pfizer-BioNTech or Moderna), and the same vaccine product as their second dose if possible.**

- **Severely Immunocompromised:** Transplants recipients (including solid organ transplant and hematopoietic stem cell transplants) • Individuals receiving treatment with an anti-CD20 agent (e.g. rituximab, ocrelizumab, ofatumumab), commonly used for conditions such as multiple sclerosis, rheumatoid arthritis, leukemias/lymphoma etc. • Individuals receiving active treatment (chemotherapy, targeted therapies, immunotherapy) for malignant hematologic disorders (e.g. Acute myeloid leukemia, chronic myeloid leukemia, acute lymphoblastic leukemia, chronic lymphocytic leukemia) *The third dose should be offered at least two months after the second dose for the above groups, and exact timing should be decided with the treating provider in order to optimize the immune response from the vaccine series and minimize delays in management of their underlying condition.*

- **Vulnerable Elderly in High-Risk Congregate Settings:** Residents of Long-Term Care Homes (LTCH), High-Risk Retirement Homes (RH) and Elder Care Lodges. *The recommended interval for residents of LTCH, High-Risk RH and Elder Care Lodges is at least 5 months after the second dose. This is consistent with the schedule of other vaccines that similarly utilize a third dose to boost the immune response to a primary series.* [9]

Reference the guidance document COVID-19 Vaccination Recommendations for Special Populations regularly for updates on evolving changes.

- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.[2]
- Clients receiving anticoagulant therapy can be immunized if they are optimally managed, and after immunization they should be advised to apply firm pressure to the injection site for 5 to 10 minutes.[2]
- Clients who have received a dose of another vaccine in the previous 14 days should have their vaccination postponed until 14 days after they received that vaccine.

- In the absence of evidence, it would be prudent to wait for a period of at least 28 days after each vaccine dose of an mRNA or viral vector COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to elicitation of an inflammatory cytokine response. It would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to a particulate vaccine.[2]
- The Pfizer-BioNTech COVID-19 should not be given simultaneously with other vaccines (live or inactivated).[2]
- If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination.[2]
- For more information on the administration of COVID-19 vaccines, please refer to the NACI document: Recommendations on the use of COVID-19 vaccines, 2021-07-22 (or as current).
- If this is the individual's second dose and they received the AstraZeneca vaccine for their first dose, ensure the client has read and understood the *COVID-19 Vaccine Information for Individuals who received a First Dose of the AstraZeneca/COVISHEIELD information sheet from the Ministry of Health.*

Obtaining Consent

Appropriate informed consent must be obtained as per the *Guidelines for Implementing the Order/Delegated Procedure* and the client must NOT have any contraindications.

Guidelines for Implementing the Order/Delegated Procedure

Nurses and nursing students are expected to prepare and administer vaccine(s) to clients in a safe, effective, and ethical manner, and to be accountable for their actions. Nurses and nursing students are expected to meet the CNO's Medication Practice Standard by performing all the administration and verification steps to minimize the chance of error.

Nurses and nursing students are expected to consult with their Manager or designate if unable to perform their nursing duties in a safe and effective manner.

Responsibilities of the nurse and nursing student who implement the intervention include the following:

- Clarify that informed consent has been obtained
- Assess the client to determine whether the specific client conditions and any situational circumstances identified in the directive have been met
- Know the risks to the client of implementing the Order/Delegated Procedure
- Possess the knowledge, skills and judgement required to implement the directive

safely
- Know the predictability of the outcomes of the intervention
- Determine whether management of the possible outcomes is within their practice; if so whether they are competent to provide management of outcomes and if not, whether the appropriate resources are available to assist asrequired.

Administration of vaccine must be in accordance with the manufacturers' product information monographs and the NACI's Recommendations on the use of COVID-19 vaccine(s).[2]

At all clinics where immunizing agents are administered, the (Agency Designate) will be available for consultation.

Informed Consent

To obtain informed consent, the nurse and/or nursing student must ensure:

- The purpose of the immunization, desired outcome, risks, and benefits are reviewed.
- The client has read and understood the information on the appropriate COVID-19 Vaccine Information Sheet(s). If the client cannot read the sheet, it should be read or explained to them. Thenurse must ensure the client has no contraindications to the vaccine as specified in the "Contraindications" section of this Medical Directive and query regarding current health (e.g., immunosuppression) and precautions.
- The client has had the opportunity to ask questions about the vaccine andhad these questions answered to theirsatisfaction.
- The client has provided informed written or verbal consent to the nurse administering vaccine.

Capacity to provide consent

A client is capable of giving consent if they understand the information that is being presented to them and appreciate the foreseeable consequences of their decision or lack of decision.

When in doubt about informed consent or a medical condition of the client, do not administer the vaccine and consult with the

(Agency Designate)

Pfizer-BioNTech COVID-19 Vaccine

Dose and Schedule for the Pfizer-BioNTech COVID-19 Vaccine:

Dose:

- 30 mcg of SARS-CoV-2 spike protein mRNA.

Volume:

- 0.3 mL

Schedule:

- 2 doses
    - Minimum interval 19 days apart
    - Authorized interval 21 days apart
    - Alternate interval 28 days apart [2]
- 3 doses
    - Severely immunocompromised: *The third dose should be offered at least two months after the second dose and exact timing should be decided with the treating provider in order to optimize the immune response from the vaccine series.* [9]
    - Vulnerable Elderly in High-Risk Congregate Settings: *The recommended interval is at least 5 months after the second dose.* [9]

Preparation and Administration of the Pfizer-BioNTech COVID-19 Vaccine

Refer to the Administration of Pfizer-BioNTech COVID-19 Vaccine guidance document https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_Pfizer_vaccine_admin.pdf with additional information on preparation, dosage forms, strengths, composition, and packaging found in the vaccine product monograph https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf

Storage Requirements and Additional Doses from Vaccine Vials

Refer to the Vaccine Storage and Handling guidance document https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/vaccine_storage_handling_pfizer_moderna.pdf

Documentation and Communication

Documentation of administered doses into the COVax database post-vaccination should be completed following the (Named Agency) procedure and the College of Nurses of Ontario's Documentation Practice Standard.] [6]

Adverse Reactions

The following adverse events have been reported as being common, very common or uncommon after either dose of the Pfizer-BioNTech COVID-19 vaccine: [2]

Very common: may affect more than 1 in 10 people

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- diarrhea

Common: may affect more than 1 in 100 and up to 1 in 10 people

- injection site redness
- injection site swelling
- nausea
- vomiting

Uncommon: may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell
- arm pain[1]

Recommendations for the post-vaccination observation period for other vaccines during the pandemic, such as for influenza vaccine, should continue to be followed.[2] Therefore, advise clients to remain in the post-vaccination waiting area for the length of time as recommended in the National Advisory Committee on Immunization (NACI) *Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic.*[4]

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the (Agency designate) shall be consulted prior to vaccination, to determine the appropriateness of the vaccination, the option of vaccination in a controlled setting and/or the use of an extended post-vaccination observation period.

As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine.[5] Specifically, the client should be monitored for:

- Hives
- Swelling of the mouth and throat

- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions (seizures)
- A fast heartbeat [1]
- Dizziness and weakness [1]

If a reaction as described above occurs while at an (above named agency), refer to the *Medical Directive for Anaphylaxis Management or internal policies.*

Adverse events/reactions must be documented, reported to the Renfrew County and District Health Unit.

Approving Physician(s)/Authorizer(s):

NAME: **SIGNATURE:**	**DATE:** YYYY/MM/DD

Appendix A – Components of the Pfizer-BioNTech COVID-19 Vaccine and its Packaging

For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.[2]

Potential non-medicinal ingredients in the vaccine or its container known to cause type 1 hypersensitivity reactions ranging from mild cutaneous reactions to anaphylaxis includes the following (which may not be a complete list):

- polyethylene glycol (PEG)[2]

The full list of non-medical ingredients is as follows:[1]

- ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- dibasic sodium phosphate dihydrate
- monobasic potassium phosphate
- potassium chloride
- sodium chloride
- Sucrose
- Water for injection

Pfizer-BioNTech COVID-19 Vaccine does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials. The glass vials have a stopper which does not contain natural rubber latex.[1]

Appendix B - Immunosuppression

- Long-term immunosuppressive therapy is used for various disease conditions including cancer, organ transplantation, GVHD following HSCT, and chronic inflammatory conditions (e.g., inflammatory bowel disease, inflammatory arthritis, psoriasis, systemic lupus erythematosus). Therapies include cancer chemotherapy, radiation therapy, long term high-dose steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), cytotoxic drugs, calcineurin inhibitors, biological response modifiers and antibodies that target lymphocytes.
- In general, if a patient is 3 months post-chemotherapy and the cancer is in remission, or if immunosuppression has been discontinued for at least 3 months (6 months or more for anti-B cell antibodies), the person is no longer considered immunocompromised.
- Individuals living with HIV that are considered immunocompetent can be vaccinated. Individuals with stable Hepatitis B or C infection can also be vaccinated. [8]
- If there is uncertainty regarding whether or not a client qualifies as being immunosuppressed, consult your medical supervisor.

References

1. Product Monograph- Pfizer-BioNTech COVID-19 Vaccine
2. NACI's Recommendations on the use of COVID-19 vaccine(s)
3. NACI's Guidance on the Prioritization of key populations for COVID-19 Vaccine(s)
4. Recommendations on the Duration of the Post-vaccination Observation Period for Influenza Vaccination during the COVID-19 Pandemic
5. Health Protection and Promotion Act
6. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019.
7. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine-relevant information and planning resources
8. Canadian Immunization Guide, Immunization of Immunocompromised Persons Part 3- Vaccination of Specific Populations
9. Ministry of Health and Long-Term Care Guidance document: COVID-19 Vaccination Recommendations for Special Populations. Version 6.0 August 17, 2021.
10. Ministry of Health and Long-Term Care Guidance document COVID-19 Vaccine: Allergy Form. Version 3.0 March 11, 2021-or as current.
11. Ministry of Health and Long-Term Care Guidance Document: COVID-19: Vaccine Storage and Handling Guidance. Version 6.1 June 24, 2021.
12. NACI Rapid Response: Interchangeability of Authorized COVID-19 Vaccines.
13. Ministry of Health Memorandum: Ontario COVID-19 Vaccine Program. August 17, 2021
14. Ministry of Health and Long-Term Care Guidance Document: COVID-19 Vaccine Information Sheet. Version 10.0 August 17th, 2021.